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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,923	10/23/2003	Kevin M. Klucher	02-04	8461

7590 01/10/2006

Deborah A. Sawislak
ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102

EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,923	KLUCHER ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/04/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

1a. Applicant's election without traverse of the invention of Group XI (original claims 10-17, 28, 30-32, 42, 44-46, 55, 57-61, new claims 62-66), filed in the reply filed on 27 October 2005 is acknowledged.

1b. The preliminary amendment filed on 27 October 2005, canceling claims 1-61 and adding claims 62-66 is acknowledged. Thus, claims 62-66 are pending and under consideration by the Examiner.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted 04 May 2005 has been received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits. Applicants submitted a request to consider U.S. Provisional Application Number 60/700,905 filed 20 July 2005, however, Applicants did not cite said provisional application on a 1449 form.

Claim rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 62-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing replication of several viruses (HBV, HCV, EMCV, BVDV and HHV-8) *in-vitro*, by contacting said viruses with the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:34, does

not reasonably provide enablement for a method treating a viral infection comprising administering to an immuno- compromised mammal with a viral infection, a therapeutically effective amount of a polypeptide comprising an amino acid of SEQ ID NO:34.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, practice the invention commensurate in scope with these claims.

Claim 62 is drawn to a method of treating viral infection by administering the polypeptide of SEQ ID NO:34 (the instant specification describes the polypeptide of SEQ ID NO:34 as being IL29 wherein the N-terminal Met is present), to an immuno-compromised mammal, however, the specification does not disclose that the administration of the polypeptide of SEQ ID NO:34 treats viral infection, *in-vivo*. The instant specification discloses that IL-29 and mutant of IL-29 reduce the replication of several viruses, such as HBV, HCV, EMCV, BVDV and HHV-8, (see examples 3, 10, 11, 14 and 22 of the instant specification). The instant specification also discloses that IL-29 was not effective in reducing the replication of "all possible" viruses, because it discloses that IL-29 has a very high EC50 for some viruses, while it has low EC50 others, (see table 18). Therefore, while the polypeptide of SEQ ID NO:34 might be effective in reducing the replication of some viruses *in-vitro*, it is not effective in reducing "all possible" viruses. Furthermore, the instant specification does not disclose the administration of the polypeptide of SEQ ID NO:34, to an immuno- compromised mammal with a viral infection, results in treating said viral infection. The instant

in-vivo examples (Examples 21 and 22), however, while these two examples disclose a procedure and a regimen for measuring the in-vivo anti viral activity of IL-29, the examples fail to disclose any results. Accordingly, the instant specification fails to enable a method of treating using IL-29. The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant case, it is not predictable whether the administration of the polypeptide of SEQ ID NO:34 into a mammal would result in the treatment of "all possible" viral infections. Although the instant specification discloses that IL-29 (SEQ ID NO:34) is effective in reducing the replication of several viruses, it also discloses that it was not effective in reducing the replication of "all possible" viruses, (see table 18). Due to the lack of guidance as to which viral infections should the polypeptide of SEQ ID NO:34 be used to treat, the complex nature of the invention, the state of the prior art which is silent regarding the claimed method, and the unpredictability of the effects of the administration of the polypeptide of SEQ ID NO: 34 into a mammal, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Therefore, the instant specification only enables for a method of reducing replication of several viruses (HBV, HCV, EMCV, BVDV and HHV-8) in-vitro, by contacting said viruses with the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:34, however the breadth of the claims are not enabled.

Claim Rejections - 35 U.S.C. § 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 62-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claim 62 recites in line 3, ".....a polypeptide comprising ***an*** amino acid sequence of SEQ ID NO:34", however, this renders the claim vague and indefinite, because it is unclear whether only part of the polypeptide of SEQ ID NO:34 is being referred to. . It is suggested that the claim be amended to recite the article "***the",*** when referring to a specific sequence, for example ".....the amino acid sequence of SEQ ID NO:34....". Appropriate correction is required.

Claims 63-66 are vague and indefinite so far as they depend from claim 62 for the limitations set forth directly above.

Conclusion:

5. No claim is allowed.

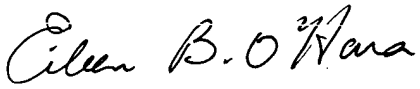
Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
09 January 2006



EILEEN B. O'HARA
PATENT EXAMINER